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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/589,357

10/02/2006

Tadashi Goino

U017569-3

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05/28/2010

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NEW YORK, NY 10023

EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

05/28/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/589,357 | Applicant(s) GOINO, TADASHI | |
| | Examiner Randall Winston | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1009, 1209</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of receipt and entry of the response to the amendment filed on 02/16/2010.

The rejections made under 35 USC 112, second paragraph, and 35 USC 103(a) set forth in the previous office action have been overcome.

Claims 1, 9-13 and new claim 14 have been examined on the merits (Claims 3 remains withdrawn as being drawn to a nonelected invention).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 9-14 stand rejected under 35 USC 103(a) for being unpatentable over Kouge et al (US 20040029955) in view of Huffstutler (US 5,466,455), Son (Derwent ACC NO 2002-146031 and/or KR 200108366A, see abstract) and Yuan (US 20020136785).

Applicant claims composition and/or method of preparation (i.e. at a claimed pH) comprising a hot water extract component of the carpophore (i.e. carpophore is the fruit body of the fungus) of the elected species of *Ganoderma lucidum*, *Coriolus Versicolor*, *Phellinus linteus*, and a hot water extract of the root of *Panax japonicus* and also

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included within the claimed composition and/or method is a hot water extract of a ginseng root is apparently claimed.

Kouge teaches a composition and/or method of preparation (i.e. at a pH) comprising a water extract component of the fruit bodies of either *Ganoderma lucidum* and/or *Coriolus Versicolor* and/or *Phenllinus linteus* to treat vascular related diseases such as malignant tumor or tumor growth inhibition of diabetic retinopathy etc (see, e.g. entire document including abstract paragraph 0013, 0029 and examples). Kouge, however, does not expressly teach within its claimed composition and/or method of a hot water extract of root of *Panax japonicus* and also the preparation of a hot water extract of a ginseng root to treat vascular related diseases such as a malignant tumor or tumor growth inhibition or diabetic retinopathy etc..

Huffstutler beneficially teaches a hot water extract of the root or *Panax japonicus* to treat vascular related diseases such as tumors (see, entire patent including claims claim1(a),(b),(fl) and claims 5 and 6)

Son beneficially teaches a hot water extract of a ginseng to treat vascular related diseases such as a malignant tumor (see, e.g. abstract).

Yuan also beneficially teaches a water extract of a ginseng root to treat vascular related diseases that causes diabetic retinopathy (see, e.g. entire document including abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kouge's composition and/or method teachings to include the other vascular related active ingredients of *Panax japonicus* and ginseng as taught

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by Huffstutler, Son and Yuan because combining the above references claimed active ingredients and/or teachings would create the overall claimed composition and/or method of preparation comprising all of the claimed active ingredients and/or all of the claimed active preparation steps to treat vascular related diseases such as a malignant tumor or tumor growth inhibition of diabetic retinopathy etc (please note that the instantly disclosed water fungus extract extracted in a similar water extraction method as the claimed invention's water extraction method would intrinsically contained the claimed oxidation-reduction potential of an aqueous solution properties). Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose (treat vascular related diseases)." Furthermore, the adjustments of other conventional working conditions (i.e. the modification of pH and heating the fungus with water because hot water is well known to aid in obtaining claimed active ingredients from fungus and determining suitable amount/ranges of each active ingredient within the claimed composition), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Please note, the intended use of the above claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is intrinsic to the composition reasonably suggested by the cited references, as a whole. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655